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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/687,951	10/13/2000	Jeffrey L. Cleland	GEN02-002-US	8871

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EXAMINER	
KAM, CHIH MIN	

ART UNIT	PAPER NUMBER
1656	

MAIL DATE	DELIVERY MODE
01/14/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/687,951	CLELAND ET AL.	
	Examiner	Art Unit	
	Chih-Min Kam	1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 November 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *20,22,23,25-29,31,33,34,36 and 40-43* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *20,22,23,25-29,31,33,34,36 and 40-43* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *11/2/07*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. The Request for Continued Examination (RCE) filed on November 2, 2007 under 37 CFR 1.114 is acknowledged. An action on the RCE follows.

Status of the Claims

2. Claims 20, 22-23, 25-29, 31, 33-34, 36 and 40-43 are pending, and claims 20, 22-23, 25-29, 31, 33-34, 36 and 40-43 are examined.

Information Disclosure Statement (IDS)

3. The references listed on the IDS filed November 2, 2007 have been considered and signed.

New Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 20, 22-23, 25-29, 31, 33-34, 36 and 40-43 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 20, 22-23, 25-29, 31, 33-34, 36 and 40-43 are directed to an injectable formulation comprising: (a) an injection vehicle comprising hyaluronic acid dissolved in a physiological buffer at a concentration of about 0.01 to about 3 percent weight per volume; and (b) particles comprising: (i) a first component that is a biologically active agent; and (ii) a second

component that is a biocompatible polymeric matrix, wherein the concentration of the polymeric matrix is about 1 mg/mL to about 500 mg/mL of formulation; and a method for administering a biologically active agent, the method comprising injecting the formulation comprising the injection vehicle and the particles.

The specification indicates pharmaceutical formulations of the invention comprise the injection vehicle of the invention, particles, and a biologically active agent. The particles and the biologically active agent can be a single component (i.e., the biologically active agent can be in particulate form) or two different components. Examples of the latter include embodiments in which the biologically active agent is coated on, or dispersed within, the particles. Preferred embodiments employ microparticles made up of a polymeric matrix having a biologically active agent dispersed therein. The concentration of particulate/biologically active agent component(s) depends on the desired dose and the maximum amount of the component(s) that can be injected. For example, polymeric microparticles including a biologically active agent dispersed therein are generally employed at concentrations between about 1 mg/mL and about 500 mg/mL and more preferably between about 50 mg/mL to about 150 mg/mL (page 8, line 22-page 9, line 4; Examples 1-7). The specification does not indicate the concentration of the polymeric matrix is about 1 mg/mL to about 500 mg/mL of formulation. The lack of description of the concentration of the polymeric matrix is about 1 mg/mL to about 500 mg/mL of formulation, and the lack of representative species for the concentration of the polymeric matrix, as encompassed by the claims, applicants have failed to sufficiently describe the claimed invention, in such full, clear, concise terms that a skilled artisan would not recognize applicants were in possession of the claimed invention.

Claim Rejections-Obviousness Type Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

5. Claims 22-23, 25-29, 31, 33-34, 36 and 43 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 4 and 21-41 of co-pending application 11/614,462 (based on the amendment filed 9/20/07). Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 22-23, 25-29, 31, 33-34, 36 and 43 in the instant application disclose a injectable formulation comprising: (a) an injection vehicle comprising hyaluronic acid dissolved in a physiological buffer at a concentration of about 0.01 to about 3 percent weight per volume; and (b) particles comprising: (i) a first component that is a biologically active agent; and (ii) a second component that is a biocompatible polymeric matrix, wherein the concentration of the polymeric matrix is about 1 mg/mL to about 500 mg/mL of formulation; and the specification indicates the invention also provide the related kits comprising articles of manufacture (e.g., a container) including the injection vehicles and formulation (page 15, line 23-page 16, line 6). This is obvious variation in view of claims 4 and 21-41 of the co-pending application which disclose a

pharmaceutical formulation comprising: an effective amount of a biologically active agent in particulate form or coated on, dispersed within, or accompanied by particles and an injection vehicle comprising a hyaluronic acid; or a kit comprising: (a) an injection vehicle comprising hyaluronic acid dissolved in a physiological buffer at a concentration of about 0.01 to about 3 percent weight per volume; and (b) particles comprising: (i) a first component that is a biologically active agent; and (ii) a second component that is a biocompatible polymeric matrix, wherein the concentration of the polymeric matrix is about 1 mg/mL to about 500 mg/mL of formulation; wherein (a) and (b) are dispersed in one or two containers adapted for simultaneous administration of (a) and (b) to an animal. Both sets of claims are directed to an injectable formulation comprising an injectable vehicle and particles comprising an active agent; or a related kit comprising the injectable formulation. Thus, claims 22-23, 25-29, 31, 33-34, 36 and 43 in present application and claims 4 and 21-41 in the co-pending application are obvious variations of an injectable formulation comprising an injectable vehicle and particles comprising an active agent.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

6. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chih-Min Kam whose telephone number is (571) 272-0948. The examiner can normally be reached on 8.00-4:30, Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleen Bragdon can be reached at 571-272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Chih-Min Kam, Ph. D.
Primary Patent Examiner

CHIH-MIN KAM
PRIMARY EXAMINER

CMK
January 10, 2008